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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,883	12/27/2005	Frederick John Rowell	330499.00040	9715

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PATENT ADMINISTRATOR
KATTEN MUCHIN ROSENMAN LLP
1025 THOMAS JEFFERSON STREET, N.W.
EAST LOBBY: SUITE 700
WASHINGTON, DC 20007-5201

EXAMINER

DIRAMIO, JACQUELINE A

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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10/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,883	ROWELL, FREDERICK JOHN	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,10 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicant's amendments to claims 1, 3 – 6, 9 and 10, as well as the cancellation of claims 2, 7, 8 and 19 and addition of new claims 20 – 25 are acknowledged.

Currently, claims 1, 3 – 6, 9, 10 and 20 – 25 are pending and under examination. Claims 11 – 18 are acknowledged as withdrawn as drawn to a non-elected invention.

Withdrawn Objections and Rejections

The previous objections to the drawings, specification and claims are withdrawn in view of Applicant's amendments and arguments filed July 9, 2007.

All previous rejections of the claims under 35 U.S.C. 112, second paragraph, are withdrawn in view of Applicant's amendments filed July 9, 2007.

The previous rejection of claims 1 – 7, 9, 10 and 19 under 35 U.S.C. 102(b) as being anticipated by Geisburg (US 6,287,875) is withdrawn in view of Applicant's amendments and arguments filed July 9, 2007. Applicant's amendment to claim 1 that requires "the flowable component" to be "denser than the buffer solution and which slowly rolls over the planar surface during use" is not taught by the Geisburg reference, which requires the "flowable component" to flow through the solid support by capillary action (see Example 1, in particular). Therefore, this rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3 – 6, 9, 10, 20, 21, and 23 – 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Markovsky et al. (US 2003/0207442).

Markovsky et al. teach a test device (affinity-chromatography assay system) comprising an immobilized component containing an analyte conjugate (first bio-reagent) and a mobile-phase composition (flowable component) containing a complimentary labeled receptor (second bio-reagent) which is complementary to the analyte conjugate, the immobilized component is supported on a planar surface, wherein the mobile-phase composition is dense and adapted to flow down or over the planar surface during use (see Figure 1; and paragraphs [0006], [0007], [0009]-[0011], [0041], [0042], [0050], [0053]-[0055], [0058]-[0060], [0063], [0065], [0068], [0070], [0077], [0084], and [0085]).

With respect to Applicant's claims 3 and 23, the analyte conjugate and the complimentary labeled receptor can comprise antigens and antibodies (see Example #1).

With respect to Applicant's claim 4, the mobile-phase composition is retained in a discrete volume as it rolls over the planar surface and does not diffuse (see paragraphs [0050], [0060], [0084] and [0085]).

With respect to Applicant's claim 5, the mobile-phase composition can include a buffer of optimal pH, a detergent, and a protein, such as BSA (bio-polymer) (see paragraphs [0053]-[0058]).

With respect to Applicant's claim 6, the immobilized component is attracted to the mobile-phase composition via the interaction of specific binding between two members of a ligand-receptor pair (see paragraphs [0007], [0009], [0070], [0084] and [0085]).

With respect to Applicant's claims 9 and 24, the test device performs a non-competitive assay using appropriate combinations of labeled antigen or labeled antibody with their complementary unlabeled counterparts (see paragraphs [0070], [0084] and [0085]).

With respect to Applicant's claims 10 and 25, the label is a fluorescent or colored label (see paragraphs [0054], [0057], and [0062]).

With respect to Applicant's claims 20 and 21, the planar surface can comprise a dip strip, as well as a membrane attached to a planar surface (see Figures 2-10; and paragraph [0010]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Markovsky et al. (US 2003/0207442) in view of Yu (US 6,723,500).

The Markovsky et al. reference, which was discussed in the 102(e) rejection above, teaches that the membrane is wettable, but fails to teach that the membrane is also hydrophobic.

Yu teaches test strips containing a plurality of reaction zones that are defined by a hydrophobic barrier. A hydrophobic composition is utilized to separate the hydrophilic reaction zones contained on the matrix (membrane) of the test strip, in order to create a barrier between each of the reaction zones (see column 10, lines 34-65). The reaction zones contain various compositions to test for one or more analytes. In some embodiments, the test reagents are the same in the reaction zones in order to create a multi-use test strip. In other embodiments, the test reagents are different in the reaction zones to assay for a panel or plurality of different analytes (see column 8, lines 28-40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a membrane that is both hydrophobic and wettable (hydrophilic) as the membrane in the test device of Markovsky et al. as taught by Yu because Yu teaches the benefit of using a hydrophobic composition on a membrane in order to create a barrier between a plurality of hydrophilic (wetable) reaction zones that each contain a composition to test for one or more analytes of interest.

Response to Arguments

Applicant's arguments filed July 9, 2007 have been fully considered but they are not persuasive with respect to the Markovsky et al. reference. Applicant argues (see p9) that Markovsky et al. fail to teach the limitation that "the flowable component is denser than the buffer solution and which slowly rolls over the planar surface during use." However, this argument is not found persuasive.

Markovsky et al. teach a test device comprising a support strip that includes an immobilized component and a mobile-phase composition (flowable component). The mobile-phase composition is preferably spray dried onto a mobile-phase support that comprises an element of the support strip. The mobile-phase composition is resuspended by the addition of a liquid solution, such as a sample, and starts to move "onto" the support strip. Further, the mobile-phase reaches the test zone, moves past the control zone and "onto" an absorbent pad, which therefore, indicates that the

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mobile-phase composition is "denser" than the liquid solution and "slowly rolls over the planar surface during use" (see paragraphs [0010], [0050], [0060], [0084] and [0085]).

Additionally, Applicant's amendment that requires "the system" to be "stood in a buffer solution during use and wherein the flowable component is denser than the buffer solution" is considered an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, because Markovsky et al. teach that the mobile-phase composition moves onto the solid support after it is solubilized by a liquid solution, the test device taught by Markovsky et al. would perform as recited in Applicant's intended use limitation because the mobile-phase composition is considered "denser" than the liquid sample.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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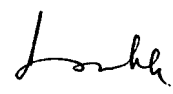
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jackie DiRamio
Patent Examiner
Art Unit 1641


LONG V. LE 09/26/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600